DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-39

DATE: **July 14, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Extension of the Clinical Laboratory Improvement Amendments (CLIA) Educational Period Regarding the Final CLIA Regulation, CMS-2226-F) -- (Refer to S&C-03-30 and S&C-04-16)

Letter Summary

- This memorandum extends the educational period beyond January, 2006 for the implementation of the final CLIA regulation quality control requirements.
- Presents revisions to the CLIA policy letters regarding the quality control requirements that became effective January 12, 2004.

Background
In this memorandum we provide official notification to the State Survey Agencies (SAs) and Centers for Medicare & Medicaid Services (CMS) regional offices (ROs) of the indefinite extension of the educational period for implementation of certain quality control (QC) requirements in the CLIA final regulation, CMS-2226-F. Due to various technological changes related to QC, we have met and collaborated with experts in the field of laboratory science. Currently, we are gathering information for evaluation and there may be a future need to make modifications to some of our QC interpretive guidelines.

Modification to "Dear Laboratory Director" Letter from August 14, 2003
We are including in this memo a letter with revised language to be used in place of letters 1 and 2 that were originally part of S&C-03-30, published 8/14/03. SAs should begin its use immediately, as applicable.

The information in the attached revised letter contains essentially the same concepts as the original letters – that is that the laboratory is meeting the requirements published in the 1992 final regulations but is not meeting certain new quality control requirements that were effective on April 24, 2003. (A CMS-2567 would be issued if the laboratory is not meeting other previously existing regulations).

The letter serves as the communication of non-compliance, but does not represent a formal deficiency citation due to our having identified new technologies and acquired additional information that may warrant changes to current guidance.

It further states that, if the laboratory director finds the manufacturer's instructions for QC acceptable, the laboratory can follow those manufacturer's instructions, as long as they meet CLIA QC requirements described in the 2003 final regulations. If there are no manufacturer's instructions for QC or they are less stringent than the 2003 CLIA regulations, the appropriate D-tags must be cited in the letter and reported to CMS as previously directed.

The language comprising the attached letter must remain as it is written except where prompted for state-specific information and the inclusion of applicable D-tags. In addition, modifications can be made for those laboratories receiving a CMS-2567, statement of deficiencies, as well as a letter.

Extension of Special Data Reporting
There is also an indefinite extension on the collection and monthly submission to CMS of the same 30 D-tags referenced in S&C-04-16, published 1/8/04. The collection of this data informs CMS of the QC activities and issues in the laboratories and may also be utilized for the development of future policies and procedures.

If you need additional clarification, please contact Judy Yost at (410) 786-3531.

Effective Date: Immediately. The SA should disseminate this information within 30 days of the date of this memorandum.

Training: This information should be shared with all appropriate survey and certification staff, their managers, QIES coordinators, and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
RO Laboratory Consultants

Attachment

Dear Laboratory Director:

Representatives of the _(State Agency)_surveyed your laboratory on_(Date)_ for CLIA purposes. Requirements contained in the former regulations, published in 1992, were met; however, the surveyor(s) identified requirements contained in the final regulations published on January 24, 2003 that were effective on April 24, 2003, that were not met.

Findings and Observations Under Revised CLIA Rules

During the exit interview, the __(State Agency)__representative discussed items regarding provisions contained in the 2003 revisions of the CLIA regulations. At present, CMS is responding to such findings by educating laboratory directors about the Quality Control (QC) regulatory requirements that may be relatively new to laboratories. We are listing these items in a letter, rather than the formal survey report as part of this educational effort. CMS expects that this process will allow laboratories to become more knowledgeable about these recent requirements in order to make informed compliance decisions.

Additionally, since the publication of the 2003 final regulations and accompanying guidelines, CMS has identified innovations in technology and received input from technical experts that may lead to further modifications of QC policies in our interpretative guidelines. CMS is also undertaking a number of processes to acquire additional information, data, and scientific input relative to such QC and technological advances in order that our policies will reflect these innovations.

Therefore, so long as laboratory directors, at a minimum, review manufacturers' QC instructions, find those instructions to reasonably monitor the accuracy of the analytic process and the laboratory then follows those manufacturers' instructions, we plan to continue the educational process noted above until any merited changes are incorporated into our guidelines, for the QC requirements contained in the 2003 modifications of the CLIA regulations.

At the time of your survey on _(date)__ your lab was not in compliance with the following provisions contained in the revised CLIA regulations:

********** You will need to customize this portion according to the compliance problems identified in each lab**********

********** Please include the remainder of the letter in your correspondence**********

Additional information concerning these items may be found on the CLIA website at www.cms.hhs.gov/clia. There are CLIA regulations, Interpretive Guidelines and several brochures on the Web site, that are helpful in understanding the revised regulations.

The _(State Agency)_ representative will be contacting you to determine if your laboratory has any questions regarding the areas identified during the survey. In the meantime, if you would like additional information or need further assistance, please contact _(name and phone number)_____.

Sincerely,

CLIA Inspector
DHSS Office of Health Facilities
Licensing and Certification